

Applicant: Bernd DORKEN et al.

Title: NOVEL CD19xCD3 SPECIFIC POLYPEPTIDES AND USES THEREOF

Appl. No.: 09/673,735

Filing Date: 12/27/2000

Examiner: Larry Ronald Helms

Art Unit: 1642

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR §1.56</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing of Request for Continued Examination (RCE).

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date May 23, 2005

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MODIFIED PTO/SB/08 (08-00) Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 09/673,735 12/27/2000 STATEMENT BY APPLICANT **Filing Date** Bernd DORKEN **First Named Inventor Group Art Unit** 1642 (use as many sheets as necessary) **Examiner Name** Larry Ronald Helms Sheet of 2 Attorney Docket Number 028622-0102

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т			
	D1	ANDERSON, P. M., et al., "G19.4(αCD3) x B43(αCD19) Monoclonal Antibody Heteroconjugate Triggers CD19 Antigen-Specific Lysis of t(4;11) Acute Lymphoblastic Leukemia Cells by Activated CD3 Antigen-Positive Cytotoxic T Cells, Blood, vol. 80, no. 11, pp. 2826-2834 (1992).				
	D2	BOHLEN, H., et al., "Cytolysis of Leukemic B-Cells by T-Cells Activated via Two Bispecific Antibodies", Cancer Research, vol. 53, pp. 4310-4314 (1993).				
	D3	HAAGEN, I., et al., "Killing of Autologous B-Lineage Malignancy Using CD3 x CD19 Bispecific Monoclonal Antibody in End Stage Leukemia and Lymphoma", Blood, vol. 84, no. pp. 556-563 (1994).				
	D4	HAAGEN, I., et al., "Unprimed CD4+ and CD8+ T cells can be rapidly activated by a CD3 x CD19 bispecific antibody to proliferate and become cytotoxic", Cancer Immunol. Immunother, vol. 39, pp. 391-396 (1994).				
	D5	DE GAST, G. C., et al., "Clinical Experience with CD3 x CD 19 Bispecific Antibodies in Patients with B Cell Malignancies", J. Hema., vol. 4, pp. 433-437 (1995).				
	D6	WEINER, G. J., et al., "Bispecific Monoclonal Antibody Therapy of B-Cell Malignancy", Leukemia and Lymphoma, vol. 16, pp. 199-207 (1995).				
	D7	HAAGEN, I., "Performance of CD3 x CD19 Bispecific Monoclonal Antibodies in B Cell Malignancy", Leukemia and Lymphoma, vol. 19, pp. 381-393 (1995)				
	D8	HAAGEN, I., et al., "The Efficacy of CD3 x CD19 Bispecific Monoclonal Antibody (BsAb) in a Clonogenic Assay: The Effect of Repeated Addition of BsAb and Interleukin-2", Blood, vol. 85, no. 11, pp. 3208-3212 (1995).				
	D9	MACK, M., et al., "A small bispecific antibody construct expressed as a functional single-chain molecule with high tumor cell cytotoxicity", Pro. Natl. Acad. Sci., vol. 92, pp. 7021-7025 (1995).				
	D10	KIPRIYANOV, S. M., et al., "Bispecific diabody for lysis of human B-lineage leukemia cells", The Fourteenth International Conf. on Adv. In the Application of Monoclonal Antibodies in Clinical Oncology", p. 29 Thira Santorini, Greece (May 5-7, 1997).				

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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TRADENS Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 09/673,735 STATEMENT BY APPLICANT **Filing Date** 12/27/2000 **First Named Inventor** Bernd DORKEN **Group Art Unit** 1642 (use as many sheets as necessary) **Examiner Name** Larry Ronald Helms 2 of Sheet Attorney Docket Number 028622-0102

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹					
,	D11	DE JONGE J., et al., "Bispecific antibody treatment of murine B cell lymphoma", Cancer Immunol. Immunother, vol. 45, pp. 162-165 (1997).				
	D12	KUFER, P., et al., "Construction and biological activity of a recombinanat bispecific single-chain antibody designed for therapy of minimal residual colorectal cancer", Cancer Immunol. Immunother, vol. 45, pp. 193-197 (1997).				
	D13	KIPRIYANOV, S. M., et al., "Bispecific CD3 x CD 19 Diabody for T Cell-Mediated Lysis of Malignant Human B Cells", Int. J. Cancer, vol. 77, pp. 763-772 (1998).				

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